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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,914	09/25/2003	Brian B. Lentricchia	11.025011	9190
38732	7590	11/18/2008		
CYTYC CORPORATION 250 CAMPUS DRIVE MARLBOROUGH, MA 01752			EXAMINER HINES, JANA A	
			ART UNIT	PAPER NUMBER
			1645	
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			11/18/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/672,914

Applicant(s)

LENTRICHIA, BRIAN B.

Examiner

JaNa Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26-28, 31, 32, 40-46, 48 and 49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-28, 31, 32, 40-46, 48 and 49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **SUPPLEMENTAL DETAILED ACTION**

### ***Amendment Entry***

1. The amendment filed May 23, 2007 has been entered. Claim 26 has been amended. Claims 1-25, 29-30, 33-39, 47 and 50 are cancelled. Claims 26-28, 31-32, 40-46 and 48-49 are under consideration in this office action.

### ***Withdrawal of Objections***

2. The objection of claims 32 and 33 has been withdrawn in view of applicants' amendments and arguments.

### ***Response to Arguments***

3. Applicant's arguments filed May 23, 2007 have been fully considered but they are not persuasive.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 26-28, 32, 40-42, 45-46 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Lentricchia et al., (US Patent 4,960,692).

The rejection was on the grounds that Lentricchia et al., anticipated the claims which are drawn to a method for assaying a sample for the presence of a target molecule comprising: providing said sample suspended in a liquid wherein said sample is suspected of comprising said target molecule; immersing a filter into said liquid containing said sample and pulling said liquid containing said sample transversely through said filter using a pressure-controlling apparatus connected to said filter, wherein said filter comprises a sensor molecule attached thereto and said sensor molecule is capable of specifically binding to said target molecule, if present; binding of said target molecule to said sensor molecule; removing said filter from said liquid; detecting the presence of said target molecule specifically bound to said sensor molecule on said filter. The rejection was also on the grounds that Lentricchia et al., taught the sensor molecule, the target molecule, control samples, secondary sensors, and secondary fluorophore labels.

#### *Response to Arguments*

5. The rejection of claims 26-28, 32, 40-42, 45-46 and 49 under 35 U.S.C. 102(b) as being anticipated by Lentricchia et al., (US Patent 4,960,692) is maintained for reasons of record.

Applicants' argue that Lentricchia et al., do not teach or suggest immersing the filter into a liquid. However, "immerse" simply means to cover in liquid. Example 1 teach that the entire liquid sample and filter were agitated and incubated, thereby allowing the filter to be immersed by the liquid. Example 1 also states that the number of particles retained s detectable by incubating the filter itself with the substrate mixture. Example 3 teaches the filters being contained within filter holders and the liquid samples were allowed to completely cover the filter within the holder. Therefore Lentricchia et al., teach immersion of the filter with the sample in

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order to contact of the sensor molecule and target molecule. Furthermore, Lentricchia et al., clearly teach contact of the sample and filter.

Applicants' assert that Lentricchia et al., do not teach or suggest a method of pulling liquid containing sample transversely through the filter using a pressure-controlling apparatus connected to the filter and that the syringe of Lentricchia et al., does meet the limitation of the claim. Lentricchia et al., specifically states that the reaction between the sensor molecule and target is conducted by passing the reaction mixture through the filter by action of pressure or vacuum (col. 4, lines 34-36). Furthermore, in response to applicant's argument, the recitation of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this the syringe or tube of Lentricchia et al., meet the limitation of a pressure-controlling apparatus connected to said filter capable of pulling said liquid containing said sample transversely through said filter. Finally, the Swinney type holder of the filter, not only houses the filter but clearly allows for the filter to be immersed and connected with a pressure-controlling apparatus connected to said filter capable of pulling said liquid containing said sample transversely through said filter. Therefore, applicants' argument is not persuasive, since Lentricchia et al., specifically recites pulling liquid containing sample transversely through the filter using a pressure-controlling apparatus connected to the filter.

Applicants' urge that Lentricchia et al., do not teach or suggest removing the filter from the liquid and detecting the presence of the target molecule. However, Lentricchia et al., clearly states detecting antibodies or the like on the membrane filter (col.4, lines 52-65). The prior art of

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Lentrichia et al., teach allowing a reaction of the binding pair, the liquids are withdrawn from the apparatus compartment by vacuum, with the particles retained on the filter followed by the detection of labels. Applicants have continually stated that Lentrichia et al., teach sampling passes through the filter, therefore, the filter is no longer in contact with the removed liquid sample. Therefore, applicants' arguments are not persuasive and the rejection is maintained.

***Claim Rejections - 35 USC § 102***

6. Claims 26-27, 40-43, 45-46 and 48-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Mirkin et al., (US Patent 6,417,340).

The rejection was on the grounds that Mirkin et al., teach a method for assaying a sample for the presence of a target molecule comprising: providing said sample suspended in a liquid wherein said sample is suspected of comprising said target molecule; immersing a filter into said liquid containing said sample and pulling said liquid containing said sample transversely through said filter using a pressure-controlling apparatus connected to said filter, wherein said filter comprises a sensor molecule attached thereto and said sensor molecule is capable of specifically binding to said target molecule, if present; binding of said target molecule to said sensor molecule; removing said filter from said sample; detecting the presence of said target molecule specifically bound to said sensor molecule. Mirkin et al., also teach the method to include different sensors, control samples, wash steps, secondary sensors and secondary fluorophore labels.

*Response to Arguments*

7. The rejection of claims 26-27, 40-43, 45-46 and 48-49 under 35 U.S.C. 102(b) as being anticipated by Mirkin et al., (US Patent 6,417,340) is maintained for reasons of record.

Applicants' argue that Mirkin et al., do not teach or suggest immersing the filter into a liquid. Contrary to applicants' assertions, Figure 5 clearly shows a filter within a well immersed in a sample. Therefore, Applicants argument is not persuasive, since Mirkin et al., clearly teaches immersing the filter into a liquid.

Applicants' assert that Mirkin et al., do not teach contacting the sample with the filter. However Mirkin et al., clearly states the support bound component being contacted with the biological sample. Mirkin et al., teach detection is achieved between the analyte in the sample and the analyte conjugated to semiconductor nanocrystal microspheres and separation is achieved because the reacted microspheres cannot pass through the filter. Mirkin et al., teaches that detection takes place on the filter. Therefore, Applicants argument is not persuasive, since the sample clearly comes in contact with the filter to thereby allow for detection on the filter. Thus, Mirkin et al., teach the invention and applicants arguments are not persuasive and the rejection is maintained.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lentricchia et al., (US Patent 4,960,692) in view of Hurley et al., (US Patent 5,256,571).

The rejection was on the grounds that it would have been prima facie obvious at the time of applicants invention to modify the method for assaying a sample for the presence of a target molecule comprising the claimed steps as taught by Lentricchia et al., to further include using a water-soluble alcohol preserving solution as taught by Hurley et al.

#### ***Response to Arguments***

9. The rejection of claim 44 under 35 U.S.C. 103(a) as being unpatentable over Lentricchia et al., (US Patent 4,960,692) in view of Hurley et al., (US Patent 5,256,571) is maintained for reasons of record.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, no more than routine skill would have been required to incorporate the water-soluble alcohol into the sample, since the prior art teaches the beneficial effects of inhibiting bacterial growth which may affect the sterility of the sample due to preservation. Furthermore, one of ordinary skill in the art would have a reasonable expectation of success, since the prior art teaches that the solution can be used with a wide variety of cell types and

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allows the cell samples to maintain their integrity and be further analyzed without any interference from the storage and preservation. Therefore, applicants' arguments are not persuasive and the rejection is maintained.

***Conclusion***

10. No claims allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/  
Examiner, Art Unit 1645

/Mark Navarro/

Primary Examiner, Art Unit 1645